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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,590	01/16/2001	Kurt M. Kessler	HMR 2041 US NP1	4289

5487 7590 07/18/2003

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EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 07/18/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/760,590

Applicant(s)  
Kresseler

Examiner  
Celia Chang

Art Unit  
1625



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 6/30/03 *declaration*.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10-19 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. An brief and Declaration were filed in Paper No. 16 and 17 dated June 30, 2003. The rejections and finality of the previous office action were withdrawn based on the newly acquired information. The brief is treated as a response to the previous office action.

Claims 10-19 are pending.

2. A newly acquired information on RN 113224-75-2 which is an analogous methanol solvate evidenced that the methanol solvate of the Kim '934 when take it as its face as the title compound methanol would indicate the methanol solvate of the "free base" i.e. the title compound and such solvate does exist in analogous art (see US 4,900,727, col. 5 line 34, with structural delineation from CAS). Therefor the rejection of claims 10-19 over Kim '934 is dropped.

3. The newly available information of US 6,576,647 necessitated the following new grounds of rejections.

Claims 10-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the specification no specific definition for "Form II" was made. It is unclear "what" does it mean when the claimed scope is being drawn to "Form II of (-)cis-2(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidinyl]-4H-1-benzopyran-4-one hydrochloride ethanol solvate" Is it a solvate constituting of (-)cis-2(2-chlorophenyl)-5,7-dihydroxy-8-[4R-

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(3S-hydroxy-1-methyl)piperidiny]-4H-1-benzopyran-4-one hydrochloride and solvate or is it a material comprising (-)cis-2(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidiny]-4H-1-benzopyran-4-one hydrochloride and ethanol with allowable "other" elements. Please note that in US 6,576,647 which is commonly assigned, it was defined that "Form II" as distinguished from form I is that it is a ethanol/hydrate of (-)cis-2(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidiny]-4H-1-benzopyran-4-one hydrochloride, see col. 3 lines 47-50. In addition the '647 ethanol/hydrate "form II" has identical x-ray diffraction pattern and was made by the identical procedure (see columns 6-8 example 4).

If the example 4 of US 6,576,647 is a (-)cis-2(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidiny]-4H-1-benzopyran-4-one hydrochloride solvate, then a 102(f) rejection is made in the following. If the example 4 of US 6,576,647 is (-)cis-2(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidiny]-4H-1-benzopyran-4-one hydrochloride ethanol hydrate as defined at column 3, then a 112 first paragraph rejection is made in the following.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(f) he did not himself invent the subject matter sought to be patented.

Claims 10-19 are rejected under 35 U.S.C. 102(f) as being anticipated by US 6,576,647,

see col 8 lines 1-4.

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Please note that the identical solvate was in possession and used by a “different” inventorship.

Claims 10-19 are directed to the same material owned and disclosed by “another” which is commonly assigned . The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

5. Claims 10-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is evidenced that in US 6,576,647 which is commonly assigned, a product was defined as “Form II” as distinguished from form I is that it is a ethanol/hydrate of (-)cis-2(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidinyl]-4H-1-benzopyran-4-one

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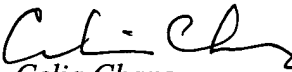
hydrochloride, see col. 3 lines 47-50. In addition the said '647 disclosed ethanol/hydrate form II has identical x-ray diffraction pattern and was made by the identical procedure (see columns 6-8 example 4). Therefore, no (-)cis-2(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidinyl]-4H-1-benzopyran-4-one hydrochloride ethanol solvate per se was made nor was procedure for making the (-)cis-2(2-chlorophenyl)-5,7-dihydroxy-8-[4R-(3S-hydroxy-1-methyl)piperidinyl]-4H-1-benzopyran-4-one hydrochloride ethanol solvate per se.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday to Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman, can be reached on (703) 308-4698. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7922.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

WP/Chang  
July 14, 2003

  
Celia Chang  
Primary Examiner  
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